EC Declaration of Conformity

By the responsible manufacturer translumina®	Translumina® GmbH Neue Rottenburger Str. 50 72379 Hechingen Germany

Zertifikat - Certificate - Certificat

Translumina® GmbH declares under its sole responsibility that the below entitled Medical Device complies to the requirements of the Medical Device Directive 93/42/EEC as amended by directive 2007/47/EC of the European Union.

The Quality Management System is in conformity with the requirements and the Conformity Assessment Procedure was followed in accordance to MDD 93/42/EEC, Annex II

The device Yukon® Choice PC Sirolimus Eluting Coronary Stent System in all variations is classified as Class III as per Annexure IX, Rule 8 and Rule 13 of MDD 93/42/EEC of June 14th 1993 as amended

The device Yukon® Choice PC Sirolimus Eluting Coronary Stent System has been manufactured as per the following standards:
EN ISO 13485, EN ISO 14971, EN 1707, EN 20594-1, EN ISO 10555-1 / 4, EN ISO 14630, EN ISO 25539-2, EN ISO 12417-1, ISO 5832-1, EN 62366, EN ISO 14155, EN ISO 10993-1 / 7, EN 868-5, EN ISO 11607-1 / 2, EN 1041, EN ISO 15223-1, EN ISO 14644-1 - 5, EN 556-1, EN ISO 11135

Issue of this certificate

Yukon® Choice PC
Sirolimus Eluting Coronary Stent System

Ref. No.:

YCPC2008	YCPC2208	YCPC2508	YCPC2708	YCPC3008	YCPC3508	YCPC4008
YCPC2012	YCPC2212	YCPC2512	YCPC2712	YCPC3012	YCPC3512	YCPC4012
YCPC2016	YCPC2216	YCPC2516	YCPC2716	YCPC3016	YCPC3516	YCPC4016
YCPC2018	YCPC2218	YCPC2518	YCPC2718	YCPC3018	YCPC3518	YCPC4018
YCPC2021	YCPC2221	YCPC2521	YCPC2721	YCPC3021	YCPC3521	YCPC4021
YCPC2024	YCPC2224	YCPC2524	YCPC2724	YCPC3024	YCPC3524	YCPC4024
YCPC2028	YCPC2228	YCPC2528	YCPC2728	YCPC3028	YCPC3528	YCPC4028
YCPC2032	YCPC2232	YCPC2532	YCPC2732	YCPC3032	YCPC3532	YCPC4032
			YCPC2740	YCPC3040	YCPC3540	YCPC4040

Certificate Registration Number	17 0353 QS/NB (EC Certificate - Full Quality Assurance System) 17 0354 CN/NB (EC Design-Examination Certificate)
Notified Body's No. Notified Body	1023 ITC Zlín třída Tomáše Bati 299 Louky 763 02 Zlín Czech Republic www.itczlin.cz

Validity of this certificate:

2017-07-31 - 2022-07-30

Hechingen, 2017-08-02

Eric Kumpa
Manager QA/RA

Dr. Boris Behnisch
Business Development

[Vers.2014/01]
This document has to be maintained at least five years after the last production of the concerned product was achieved.

EC Declaration of Conformity

By the responsible manufacturer: translumina®	Translumina® GmbH Neue Rottenburger Str. 50 72379 Hechingen Germany

Zertifikat - Certificate - Certificat

Translumina® GmbH declares under its sole responsibility that the below entitled Medical Device complies to the requirements of the Medical Device Directive 93/42/EEC as amended by directive 2007/47/EC of the European Union.

The Quality Management System is in conformity with the requirements and the Conformity Assessment Procedure was followed in accordance to MDD 93/42/EEC, Annex II.

The device **Yukon® Chrome PC Sirolimus Eluting Coronary Stent System** in all variations is classified as Class III as per Annexure IX, Rule 8 and Rule 13 of MDD 93/42/EEC of June 14th 1993 as amended.

The device **Yukon® Chrome PC Sirolimus Eluting** Coronary Stent System has been manufactured as per the following standards:
EN ISO 13485, EN ISO 14971, EN 1707, EN 20594-1, EN ISO 10555-1 / 4, EN ISO 14630, EN ISO 25539-2, EN ISO 12417-1, ISO 5832-5, EN 62366, EN ISO 14155, EN ISO 10993-1 / 7, EN 868-5, EN ISO 11607-1 / 2, EN 1041, EN ISO 15223-1, EN ISO 14644-1 5, EN 556-1, EN ISO 11135

Issue of this certificate

Yukon® Chrome PC
Sirolimus Eluting Coronary Stent System

Ref. No.:

T-CMG2008PC	T-CMG22508PC	T-CMG2508PC	T-CMG27508PC	T-CMG3008PC	T-CMG3508PC	T-CMG4008PC
T-CMG2012PC	T-CMG22512PC	T-CMG2512PC	T-CMG27512PC	T-CMG3012PC	T-CMG3512PC	T-CMG4012PC
T-CMG2016PC	T-CMG22516PC	T-CMG2516PC	T-CMG27516PC	T-CMG3016PC	T-CMG3516PC	T-CMG4016PC
T-CMG2018PC	T-CMG22518PC	T-CMG2518PC	T-CMG27518PC	T-CMG3018PC	T-CMG3518PC	T-CMG4018PC
T-CMG2021PC	T-CMG22521PC	T-CMG2521PC	T-CMG27521PC	T-CMG3021PC	T-CMG3521PC	T-CMG4021PC
T-CMG2024PC	T-CMG22524PC	T-CMG2524PC	T-CMG27524PC	T-CMG3024PC	T-CMG3524PC	T-CMG4024PC
T-CMG2028PC	T-CMG22528PC	T-CMG2528PC	T-CMG27528PC	T-CMG3028PC	T-CMG3528PC	T-CMG4028PC
T-CMG2032PC	T-CMG22532PC	T-CMG2532PC	T-CMG27532PC	T-CMG3032PC	T-CMG3532PC	T-CMG4032PC
			T-CMG27540PC	T-CMG3040PC	T-CMG3540PC	T-CMG4040PC

Certificate Registration Number	17 0353 QS/NB (EC Certificate - Full Quality Assurance System) 17 0355 CN/NB (EC Design-Examination Certificate)
Notified Body's No. Notified Body	1023 ITC Zlín třída Tomáše Bati 299 Louky 763 02 Zlín Czech Republic www.itczlin.cz

Validity of this certificate:

2017-07-31 - 2022-07-30

Hechingen, 2017-08-02

Eric Kumpa
Manager QA/RA

Dr. Boris Behnisch
Business Development

[Vers.2014/01]
This document has to be maintained at least five years after the last production of the concerned product was achieved.

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Design-Examination Certificate
No. 17 0354 CN/NB

issued for manufacturer

Translumina GmbH

Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

in accordance with requirements of

Directive 93/42/EEC

on medical devices, Annex II (4)

for the following product category(ies):

Sirolimus Eluting Coronary Stent System

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with MDD Annex II. The design of the devices conforms to the requirements of this Directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

Valid from: 2017-07-31
Valid until: 2022-07-30
First Issued: 2017-07-31
Revision: -

Date: 2017-07-31

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 17 0353 QS/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Product(s):

Name:	**Sirolimus Eluting Coronary Stent System**
Trade name(s):	Yukon® Choice PC
Model(s):	SV small vessel version (2,0-2,5mm) MV medium vessel version (2,75-4,0mm)
Class:	III
GMDN:	58771

Name:	**Sirolimus Eluting Coronary Stent System**
Trade name(s):	Yukon® Chrome PC
Model(s):	SV small vessel version (2,0-2,5mm) MV medium vessel version (2,75-4,0mm)
Class:	III
GMDN:	58771

Date: 2017-07-31
Revision: -

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 17 0353 QS/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Facility(ies):

Translumina GmbH
Address:
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany
Lotzenaecker 11, 72379, Hechingen, Germany
Lotzenaecker 3, 72379 Hechingen, Germany

Date: 2017-07-31
Revision: -

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 17 0353 QS/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Certificate History:

Revision	Date	Reference Number	Action
	2017-07-31	803602400	Certification

Date: 2017-07-31
Revision: -

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Design-Examination Certificate

No. 17 0355 CN/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Product:

Name:	**Sirolimus Eluting Coronary Stent System**
Trade name(s):	Yukon® Chrome PC
Model(s):	SV small vessel version (2,0-2,5mm) MV medium vessel version (2,75-4,0mm) See below the reference numbers
Class:	III
GMDN:	58771

Date: 2017-07-31
Revision:-

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Design-Examination Certificate

No. 17 0355 CN/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Reference numbers:

T-CMG2008PC	T-CMG22508PC	T-CMG2508PC	T-CMG27508PC	T-CMG3008PC	T-CMG3508PC	T-CMG4008PC
T-CMG2012PC	T-CMG22512PC	T-CMG2512PC	T-CMG27512PC	T-CMG3012PC	T-CMG3512PC	T-CMG4012PC
T-CMG2016PC	T-CMG22516PC	T-CMG2516PC	T-CMG27516PC	T-CMG3016PC	T-CMG3516PC	T-CMG4016PC
T-CMG2018PC	T-CMG22518PC	T-CMG2518PC	T-CMG27518PC	T-CMG3018PC	T-CMG3518PC	T-CMG4018PC
T-CMG2021PC	T-CMG22521PC	T-CMG2521PC	T-CMG27521PC	T-CMG3021PC	T-CMG3521PC	T-CMG4021PC
T-CMG2024PC	T-CMG22524PC	T-CMG2524PC	T-CMG27524PC	T-CMG3024PC	T-CMG3524PC	T-CMG4024PC
T-CMG2028PC	T-CMG22528PC	T-CMG2528PC	T-CMG27528PC	T-CMG3028PC	T-CMG3528PC	T-CMG4028PC
T-CMG2032PC	T-CMG22532PC	T-CMG2532PC	T-CMG27532PC	T-CMG3032PC	T-CMG3532PC	T-CMG4032PC
			T-CMG27540PC	T-CMG3040PC	T-CMG3540PC	T-CMG4040PC

Date: 2017-07-31
Revision:-

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Design-Examination Certificate

No. 17 0355 CN/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Certificate History:

Revision	Date	Reference Number	Action
	2017-07-31	803602400	Certification

Date: 2017-07-31
Revision:-

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Design-Examination Certificate

No. 17 0354 CN/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Product:

Name:	**Sirolimus Eluting Coronary Stent System**
Trade name(s):	Yukon® Choice PC
Model(s):	SV small vessel version (2,0-2,5mm) MV medium vessel version (2,75-4,0mm) See below the reference numbers
Class:	III
GMDN:	58771

Date: 2017-07-31
Revision:-

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Design-Examination Certificate

No. 17 0354 CN/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Reference numbers:

YCPC2008	YCPC2208	YCPC2508	YCPC2708	YCPC3008	YCPC3508	YCPC4008
YCPC2012	YCPC2212	YCPC2512	YCPC2712	YCPC3012	YCPC3512	YCPC4012
YCPC2016	YCPC2216	YCPC2516	YCPC2716	YCPC3016	YCPC3516	YCPC4016
YCPC2018	YCPC2218	YCPC2518	YCPC2718	YCPC3018	YCPC3518	YCPC4018
YCPC2021	YCPC2221	YCPC2521	YCPC2721	YCPC3021	YCPC3521	YCPC4021
YCPC2024	YCPC2224	YCPC2524	YCPC2724	YCPC3024	YCPC3524	YCPC4024
YCPC2028	YCPC2228	YCPC2528	YCPC2728	YCPC3028	YCPC3528	YCPC4028
YCPC2032	YCPC2232	YCPC2532	YCPC2732	YCPC3032	YCPC3532	YCPC4032
-	-	-	YCPC2740	YCPC3040	YCPC3540	YCPC4040

Date: 2017-07-31
Revision:-

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomir Čevelík
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Design-Examination Certificate

No. 17 0354 CN/NB

issued for manufacturer:

Translumina GmbH
Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Certificate History:

Revision	Date	Reference Number	Action
	2017-07-31	803602400	Certification

Date: 2017-07-31
Revision:-

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

DEKRA

translumina GmbH
Neue Rottenburger Straße 50
72379 Hechingen
Germany

Your ref.
Our ref. 2222713-TCP-R1
Tel. +31 88 96 83 009
Fax +31 88 96 83 100
E-mail medical.nl@dekra.com

Arnhem, 27 February 2018

Subject:
Certification status

To Whom It May Concern,

DEKRA Certification, in its capacity of Notified Body for Medical Devices, declares, based on the results of the inspection and assessment activities performed, in reference to the Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports between EU AIMD/MDD/IVDD Notified Body Partners and R.O.C. TFDA Authorized Medical Device GMP Auditing Organizations (TCP), the following:

The most recent audit DEKRA Certification Notified Body performed at translumina GmbH facilities was performed on 28-30 November 2018. The scope of the audit was Certification audit TCP Audit in accordance with Clients QMS and ISO 13485:2003 (RvA accredited) / R.O.C. TCP program. The results of the assessment are documented in 2222713-AR01-R1, issued on 27 February 2018.

The ISO certificate 2222713 bears the following scope:
Design, development, manufacturing and distribution of catheters and stent systems for cardiology and radiology

It covers the following products sold by translumina GmbH in R.O.C., through:
Hsin Tung Medical Co., Ltd.
7F., No. 180, Sec. 6
Zhongxiao E. Rd., Nangang Dist.
Taipei City 115
Taiwan

Product Group: Coronary Stent
Yukon® CC (bare metal stent, CoCr)
Yukon® Choice 4 (bare metal stent, stainless steel thin struts)

Product Group: PTCA Catheters
Cathy No. 4

The DEKRA Certification B.V. approved production location:
translumina GmbH
Neue Rottenburger Straße 50
72379 Hechingen
Germany

The above referenced documents are all valid documents, issued by DEKRA Certification Notified Body.

With kind regards,
DEKRA Certification B.V.

ing. A.A.M. Laan
Certification Manager Medical Devices

CERTIFICATE

Number: 2222713

The management system of:

translumina GmbH

Neue Rottenburger Straße 50
72379 Hechingen
Germany

including the implementation meets the requirements of the standard:

ISO 13485:2003

Scope:
Design, development, manufacturing and distribution of catheters and stent systems for cardiology and radiology.

Certificate expiry date: 1 March 2019
Certificate effective date: 7 February 2018
Certified since: 7 February 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

MGMT. SYS.
RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396